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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,720	07/17/2000	Martin Nicklin	MSA-021.01	7893
25181	7590	12/27/2005	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/617,720	NICKLIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 October 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 12,27,28,30 and 33-37 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 12, 27-28, 30, 33-37 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

1a. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 October 2005 has been entered.

#### ***Status of Claims:***

1b. Claims 1-11, 13-26, 29, 31-32 have been cancelled. Claims 12, 27-28, 30, 33-37 are pending and under consideration.

1c. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 10/13/2005.

(I) All of the rejections made against claim 32 are moot. Accordingly, the rejections of claim 32 made under 35 U.S.C § 102(b) as being anticipated by Jeffreys et al (Accession Number AAQ95200; 06/29/1995), and by Stausberg, (Accession Number:AI252833, 11/05/1998), are moot.

(II) The rejection of claim 33 made under 35 U.S.C § 102(a) as being anticipated by Mulero et al (16 October 1999), is withdrawn, because Mulero et al reference does not teach a nucleic acid that comprises nucleotides 1-600 of SEQ ID NO:1, as recited in claim 33.

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(III) The rejection of claims 33-37 made under 35 U.S.C § 102(e) as being anticipated by Ford et al (U.S Patent 6,294,655). (SEQ ID NO:6 of U.S Patent 6,294,655, is withdrawn, because Ford et al do not teach an isolated nucleic acid comprising nucleotides 1-600 of SEQ ID NO:1, as recited in the instant claim 33. The nucleic acid disclosed by Ford et al has gaps at positions 507 and 582. Furthermore, since claim 33 no longer recites hybridization limitation, the nucleic acid of Ford et al does not anticipate claim 33.

(IV) The rejection of claims 34-37 made under 35 U.S.C. 112, second paragraph, is withdrawn, because these claims no longer depend from cancelled claims.

(V) The rejection of claim 35 for being drawn to non-statutory subject matter, is withdrawn, since the claim now recite "an isolated host cell".

(VI) The rejection of claim 35 made under 35 U.S.C. 112, second paragraph, is withdrawn, because the claim no longer recites "or".

***Response to Amendment:***

***Claim Rejections - 35 U.S.C. § 101/112:***

3a. Claims 12, 27-28, 30 and 33-37 stand rejected under 35 U.S.C. 101, for reasons of record set forth in the office action mailed on 13 April 2005.

Applicants argue that the claimed nucleic acid is useful in diagnostic assays to diagnose or confirm that a symptomatic subject has a genetic defect in an IL-IL1 gene that causes or contributes to an inflammatory disease or disorder, particularly a genetic defect that is single nucleotide polymorphism, (SNP). Applicants submit that the specification describes a number of inflammatory diseases or disorders associated with

aberrant IL-IL1 activity, including arthritis and cites page 87 of the specification for support. Applicants further argue that it has been subsequently determined by others that specific SNP mutations in the IL-IL1 nucleic acid are associated with one form of arthritis, ankylosing spondylitis (AS). Applicants cite Timms et al reference (American Journal of Human Genetics, Vol. 75, pages 587-595, 2004). Applicants conclude that this reference should be considered in determining the specific and substantial utility of the present invention, because the specification clearly established a nexus between diagnostic use of genetic defects including SNPs, which cause or contribute to an inflammatory disease or disorder, such as arthritis.

Applicants' arguments have been considered but are not deemed persuasive. Firstly, the instant specification only makes a general reference to using the claimed nucleic acid, in diagnosing genetic defects, which cause or contribute to diseases or conditions, particularly where said conditions are caused by SNPs, (see page 9, second paragraph). However, the specification does not disclose a single specific disease that is caused by any mutation to the nucleic acid of the present invention. There is no disclosure of any specific SNPs or any diseases caused by said SNPs. Secondly, the specification does not establish a nexus between ankylosing spondylitis or any other disorder and the claimed nucleic acid. The specification lists a number of disparate diseases such as inflammatory diseases, cancer, vascular diseases and cardiac disorders, neurological diseases, AIDS, that can be diagnosed using the claimed invention (see page 87). However, the specification fails to demonstrate that the claimed nucleic acid is actually involved in any of these diseases. The specification

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does not show whether the claimed nucleic acid is over expressed or under expressed in any of the recited diseases. Thirdly, the post filing date reference cited by Applicants cannot be used to determine patentable utility for the claimed invention, because the reference does not corroborate an asserted utility. The Timms et al reference does not disclose that the nucleic acid of the instant invention is actually associated with ankylosing spondylitis. The Timms et al reference identified several SNPs of the IL-1 gene cluster and showed that several of them are associated with ankylosing spondylitis. However, the nucleic acid of the instant invention is not one of the identified SNPs, (i.e ILF5) that was shown to be associated with ankylosing spondylitis . Timms et al disclose that IL-1B and IL-1F10-3 polymorphisms were significantly associated with ankylosing spondylitis, but does not disclose the present nucleic acid plays any role in said disease. Even if the Timms et al reference did show that mutations in the claimed nucleic acid causes or contributes to a particular disease, this reference cannot be used to establish utility for the current application, because the specification does not disclose a specific mutation of the current nucleic acid that led to a specific disease. Arthritis was one of the numerous disparate diseases listed by the specification as diagnosable by the claimed nucleic acid, however, beyond these mere speculations, there was no support that the claimed nucleic acid is involved in a specific disease or disorder.

**Conclusion:**

4. No claim is allowable.

**Advisory Information:**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-

0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
21 December 2005

*Eileen B. O'Hara*  
EILEEN B. O'HARA  
PATENT EXAMINER